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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,971	10/21/2003	Chih-Ying Hsu	U 014862-0	4700

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LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

GROSS, CHRISTOPHER M

ART UNIT	PAPER NUMBER
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1639

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/690,971

4

Applicant(s)

HSU ET AL.

Examiner

Christopher M. Gross

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 17 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 17-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/17/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Responsive to communications entered 7/17/2006. Claims 1-34 are pending. Claims 17-32 are withdrawn. Claims 33-34 have been added Claims 1-16, 33-34 are under consideration.

Priority

Acknowledgment is again made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) to Taiwan patent 091125053, filed 10/25/2002.

Withdrawn Rejections

The rejection of Claims 1-5, 8-10,13,15-16 under 35 U.S.C. 102(e) as being anticipated by Martin et al (US Patent Application 2003/0082633) has been withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-5, 8-10,13,15-16 and 6 and 7 under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) in view of **O'Neill et al** (US Patent 6124092) has been withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-5, 8-10,13,15-16 and 6,7,11-12 under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) in view of **Becker et al** (US Patent 6225061) has been withdrawn in view of applicant's amendments to the claims.

The rejection of claims 1-5, 8-10,13,15-16 and 14 under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) in view of

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Montagu (US Patent 6407858) has been withdrawn in view of applicant's amendments to the claims.

New Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 8-10, 13, 15-16, 33, 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) in view of **Hornes et al** (US Patent 5512439).

This rejection is necessitated by Applicant's amendments to the claims.

The claimed invention per claim 1 is drawn to a micro-array system for a micro amount of biomolecules carrying on a bioreaction in a reaction solution, which comprises:

(a) a substrate comprising a plurality of micro-wells for receiving the reaction solution;

(b) a plurality of magnetic micro-beads placed in the reaction solution with the biomolecules attached on surfaces of the micro-beads thereof;

(c) vibration means for causing rapid back and forth movement of the substrate, to cause the biomolecules attached on the micro-beads to react evenly; and

(d) magnetic force means for removing the magnetic micro-beads from the reaction solution.

Martin et al, throughout the publication, and especially, paragraphs 0023, 0201 and 0302 disclose a chip or microtiter plate that can be associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated with microwaves.

In contrast to applicants remarks entered, 7/17/2006, see p 12 which state that the "solid-support" of Martin paragraph must comprise a reactive surface, it is the microtiter plate of Martin et al which reads on the 'a substrate comprising a plurality of micro-wells' of claim 1. Furthermore giving the claims the broadest reasonable interpretation, said microtiter plate would be expected to be "biologically inert" as set forth in claim 33 since microtiter plates are not biological and do not have enzymatic activity, etc.

The following three prong test must be satisfied for a claim to be examined under 35 USC 112 sixth paragraph:

- (A) the claim limitations must use the phrase "means for " or "step for; "
- (B) the "means for " or "step for " must be modified by functional language;
- and
- (C) the phrase "means for " or "step for " must not be modified by sufficient structure, material or acts for achieving the specified function.

It is noted that while the claim satisfies the first and second prongs, using the phrase "means for" and functional language such as for "causing rapid back and forth movement of the substrate" and "removing the magnetic micro-beads from the reaction

Where a claim element recites a function, but then goes on to elaborate sufficient structure, material, or acts to perform entirely the recited function, the claim is not in

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means-plus-function format (Cole v. Kimberly-Clark Corp., 102 F.3d 524, 531, 41 USPQ2d 101, 1006 (Fed. Cir. 1996), Laitram Corp. v. Rexnord, Inc., 939 F.2d 1533, 1536, 19 USPQ 1367, 1369 (Fed. Cir. 1991)

In the instant case, the term "magnetic force" in line 11 sets forth sufficient structure/acts because only certain types of materials possess magnetic force (e.g., ferromagnetic materials). Thus, the effect, i.e., the removal of the beads, is not open to other means like physically removing the beads without the use of a magnetic. Likewise, the term vibration in line 8 also adds sufficient structure/acts to preclude the use of sixth paragraph because not all means for causing rapid back and forth motions are available.

In conclusion, the means for language in lines 8 and 10 does not implicate 35 USC 112 sixth paragraph.

Absent evidence to the contrary, the microwave radiation inducing a vibration of Martin et al reads on 'vibration' of claim 1. Note that quiver represents an alternate definition of vibration according to the dictionary page provided by Applicant. The examiner submits that piezoelectric vibration represents a type of quivering.

The nucleic acids analyzed of Martin et al reads on the 'biomolecules' of the preamble of claim 1 and the first elected species in claim 2. The association with a solid support reads on the 'micro-beads' of claim 1.

Martin et al in paragraph 0208 disclose a type of polymerase chain reaction (PCR) with their system, reading on claim 3 and the second elected species.

Martin et al in paragraph 0120 disclose the use of a thermocouple, reading on the 'temperature control module for controlling the temperature of the reaction' of claim 10. Martin et al in paragraph 0130 disclose magnetite particles, reading on the 'magnetic beads' of claim 5. Martin et al in paragraph 0132 disclose silicon oxides, reading on the 'substrate made from silicon' of claim 4. Martin et al in paragraph 0146 disclose using a laser, reading on the 'laser source' of claim 13. Martin et al in paragraph 0220 disclose an air-tight plastic chamber, reading on the 'coverplate' of claim 15. Martin et al in paragraph 0286 and 0302 disclose painting the undersides of a microtiter plate with a barium titanate, a piezoelectric vibrator in the presence of microwaves, which reads on the 'vibrating module that is set under the substrate' of claim 8 and the electrostatic vibrator of claim 9. Martin et al in paragraph 0299 disclose a signal visualized by X-ray film, reading on the 'signal sensor' of claim 16.

Martin et al do not teach a separator device for removing magnetic beads from a reaction solution using magnetic force means or a magnet (claim 34).

Hornes et al teach, throughout the document and especially column 19, line 22, a magnet for aggregating magnetic particles.

Hornes et al also teach in example 1 the use of 1-ethyl-3-(3-dimethylaminopropyl)-carbodiimide (EDC), as set forth in claims 6 and 7.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the chip or microtiter plate associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by

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microwaves of Martin et al with magnet for aggregating magnetic particles per Hornes et al.

One of ordinary skill in the art would have been motivated to use the chip or microtiter plate associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnet for aggregating magnetic particles per Hornes et al because it would provide quick washing, allow for continuous monitoring and require less vigorous conditions, all advantageous according to Hornes in column 2, lines 15-35.

One of ordinary skill could use the chip or microtiter plate associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnet for aggregating magnetic particles per Hornes et al with a reasonable expectation of success since Hornes et al has applied magnetic particles toward nucleic acid extraction, therefore it is not unreasonable to use similar magnetic particles in the microtiter plate to analyze nucleic acids per Martin et al. Furthermore, magnetic particle separation is well established in the art.

Claims 11-12 rejected under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) **in view of Hornes et al** (US Patent 5512439) as applied to claims 1-7 8-10,13,15-16, 33, 34 above, and further in view of **Becker et al** (US Patent 6225061).

This rejection is necessitated by Applicant's amendments to the claims.

Martin et al in view of Hornes et al relied on as above.

Martin et al in view of Hornes et al do not teach a system comprising a temperature sensor, heater and cooler or the further limitation that the heater be a heating/sensor resistor, however.

Becker et al, throughout the document, and especially figure 1, teach a microchip holder comprising an integrated peltier element (for cooling) and thermistor (temperature sensing resistor), which are taken together as the temperature sensor, heater and cooler of claim 11 as well as the heating/sensor resistor of claim 12.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al plus the microchip holder comprising an integrated peltier element and thermistor of Becker et al.

One of ordinary skill in the art would have been motivated to make and use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al plus the microchip holder comprising an integrated peltier element and thermistor of Becker et al because it would be more versatile, providing any temperature, including less than ambient which is not possible with the chip system of Martin in view of Hornes et al alone.

One of ordinary skill could use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al plus the microchip holder

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comprising an integrated peltier element and thermistor of Becker et al with a reasonable expectation of success since peltier elements and thermistors are well known in the art.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Martin et al** (US Patent Application 2003/0082633) in view of **Hornes et al** (US Patent 5512439) as applied to claims 1-7 8-10,13,15-16, 33, 34 above, and further in view of **Montagu** (US Patent 6407858).

This rejection is necessitated by Applicant's amendments to the claims.

Martin et al in view of Hornes et al relied on as above.

Martin et al in view of Hornes et al does not teach a system comprising a lens, however.

Montagu throughout the publication, and especially the abstract, discusses using a microscope and biochip reader for making fluorescence measurements of biochips. Since a microscope inherently includes a lens, this is taken to be the lens of claim 14.

It would have been *prima facie* obvious for one of ordinary skill in the art, at the time the claimed invention was made to use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al employing the biochip reader of Montagu.

One of ordinary skill in the art would have been motivated to use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate

when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al, employing the biochip reader of Montagu because it would be inexpensive, as noted by Montagu in column 11, line 10-12.

One of ordinary skill could use the chip associated with a solid support (such as a bead) to analyze nucleic acids and vibrate when irradiated by microwaves of Martin et al with magnetic aggregation provided by Hornes et al, employing the biochip reader of Montagu with a reasonable expectation of success since microscopes are well known in the art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Gross whose telephone number is (571)272-4446. The examiner can normally be reached on M-F 9-5:30.

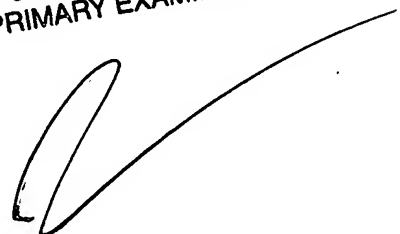
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, J. Douglas Schultz can be reached on 571 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher M Gross
Examiner
Art Unit 1639

cg

JON EPPERSON
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to be 'J. Epperson', written over the printed name and title.

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